UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

INNA DESCH,

Plaintiff,

v.

MERZ NORTH AMERICA, INC. and ULTHERA, INC.,

Defendants.

MEMORANDUM & ORDER
22-CV-02688 (HG)

HECTOR GONZALEZ, United States District Judge:

Plaintiff was treated with a medical device manufactured by Defendants and has allegedly suffered injuries resulting from that treatment. She has asserted claims for breaches of express and implied warranty, negligence, misrepresentation by omission, and strict products liability based on alleged manufacturing defects and failures to warn. ECF No. 17. Defendants have moved to dismiss these claims in full. ECF No. 18. For the reasons set forth below, the Court grants Defendants' motion in part and denies it in part. Plaintiff's claims that rely on alleged manufacturing defects are dismissed, but Plaintiff's claims survive to the extent that they rely on Defendants' alleged failure to warn the U.S. Food and Drug Administration (the "FDA") and the medical community about supposed adverse events related to Defendants' device.

FACTUAL BACKGROUND

Defendants created a medical device, which the parties refer to as the "Ulthera System," that uses ultrasound to provide "a 'non-invasive' alternative to face lifts." ECF No. 17 ¶¶ 33–34. Defendants' device has undergone several different rounds of review by the FDA. Defendants originally obtained clearance from the FDA to market their device as a Class II medical device "to lift the eyebrow." *Id.* ¶ 37. During the FDA's review process, the FDA decided that

Defendants' device was not substantially equivalent to other devices previously on the market. *Id.* ¶¶ 38–40. Accordingly, the FDA reviewed the device according to a "*de novo*" standard, rather than the "substantial equivalence" standard that typically applies to Class II devices, and when the FDA ultimately cleared Defendants' device, it published a "special controls" document with recommendations that future devices of the same type must address. *Id.* ¶¶ 16–20, 35–39.

After receiving the FDA's initial clearance, Defendants submitted several additional FDA applications, which collectively resulted in the FDA clearing Defendants to market their device for other uses: "to lift skin on the neck, lift skin under the chin[,] and to reduce lines and wrinkles on the chest." *Id.* ¶¶ 44–51. However, Defendants applied to the FDA for clearance to use the device on "the full face and neck," and the FDA denied that application, stating that the "new indication for use is not acceptable." *Id.* ¶¶ 66–69.

Plaintiff alleges that Defendants' marketing of their device was misleading in several respects. She alleges that Defendants marketed their device for use on "the entire face," despite receiving a denial of FDA clearance for that purpose. *Id.* ¶ 70. To support these allegations, Plaintiff has identified specific statements on Defendants' website and in "training materials" and a "whitepaper" that Defendants allegedly distributed to physicians. *Id.* ¶¶ 70–75, 77. Plaintiff further alleges that Defendants misleadingly marketed their device as "non-invasive" and downplayed any adverse effects as "mild and temporary in nature" on both Defendants' website and in a user manual distributed to medical providers. *Id.* ¶¶ 78–80. These promotional statements were allegedly contradicted by several specific incidents of "permanent nerve injuries" that supposedly occurred in other patients prior to Plaintiff's treatment, and which Defendants allegedly failed to report to the FDA, as required by federal regulations, or to the medical community more generally. *Id.* ¶¶ 81–85, 92–96. Finally, Plaintiff alleges that

Defendants misleadingly marketed their device as "FDA approved" even though the review process for Class II devices specifically does not result in "approval" and instead results merely in "clearance." *Id.* ¶¶ 20, 76.

In addition to alleging that Defendants' marketing was misleading, Plaintiff alleges that Defendants' manufacturing process for the device was defective. In particular, she alleges that a manufacturing defect caused the device to "deliver[] the wrong amount of energy to the wrong locations." *Id.* ¶ 221. Plaintiff's complaint does not identify a specific manufacturing defect, but she alleges that the defect occurred because of Defendants' alleged "fail[ure] to establish and maintain procedures for implementing corrective and preventative actions" during the manufacturing process, as mandated by federal regulations that require Defendants to maintain Current Good Manufacturing Practices ("CGMPs"). *Id.* ¶ 226 (citing 21 C.F.R. § 820.100(a)).

Plaintiff alleges that she received treatment from a non-party physician using the Ulthera System on her "full face"—*i.e.*, the form of treatment for which the FDA specifically declined to clear the device. *Id.* ¶¶ 68–69, 107. As a result of her treatment, Plaintiff allegedly suffered "permanent facial, eye, and nerve damage, including significant facial fat atrophy." *Id.* ¶ 125. Plaintiff has separately sued her medical providers in state court for medical malpractice and related claims. *See Desch v. Walden, et al.*, No. 525866/2021 (N.Y. Sup. Ct. Kings Cty.). Plaintiff originally commenced this lawsuit in state court as well, but Defendants properly removed Plaintiff's claims to this Court based on diversity jurisdiction because Plaintiff is a citizen of New York, and Defendants are citizens of Delaware, Arizona, and North Carolina. ECF No. 1 ¶¶ 6–9.

Plaintiff is asserting several causes of action under New York law: (i) breach of express warranty; (ii) breach of implied warranty; (iii) negligence; (iv) strict liability based on a failure to

warn theory; (v) strict liability based on an alleged manufacturing defect; and (vi) misrepresentation by omission. ECF No. 17. Defendants initially requested a pre-motion conference regarding a proposed motion to dismiss Plaintiff's original complaint, but the Court deemed a conference to be unnecessary and set a briefing schedule for Defendants' proposed motion to dismiss. ECF No. 7; ECF Order dated May 24, 2022. However, before Defendants' opening brief came due, the parties consented to Plaintiff filing an amended complaint, and the Court set a revised briefing schedule. ECF Nos. 15 & 16. Defendants thereafter filed their motion to dismiss directed at Plaintiff's amended complaint, and the Court held oral argument on the motion. ECF Nos. 17 & 18; ECF Minute Entry dated Dec. 19, 2022.

LEGAL STANDARD

To survive a motion to dismiss, a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).[1] "A claim is plausible 'when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Matson v. Bd. of Educ.*, 631 F.3d 57, 63 (2d Cir. 2011) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Although all allegations contained in a complaint are assumed to be true, this tenet is "inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678. "Although preemption is an affirmative defense, this doctrine can still support a motion to dismiss if the statute's barrier to suit is evident from the face of the complaint." *Melendez v. Sirius XM Radio, Inc.*, 50 F.4th 294, 300 (2d Cir. 2022); *see also Glover v. Bausch & Lomb Inc.*, 6 F.4th 229, 236 n.3 (2d Cir. 2021)

[1] Unless noted, case law quotations in this order accept all alterations and omit internal quotation marks, citations, and footnotes.

(confirming that this same standard applies to the question of express preemption under the Medical Device Amendments to the Food, Drug, and Cosmetic Act).

DISCUSSION

I. Plaintiff's Claims Are Not Expressly Preempted by Federal Law

A. Legal Standard Applicable to Preemption

Defendants argue that all of Plaintiff's claims are preempted by federal law. ECF No. 18-1 at 10–13. The Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act provide that where the Act imposes a specific requirement for a type of device, any state law that purports to apply to the device is preempted to the extent the state law: (i) imposes an obligation that "is different from, or in addition to, any requirement" under the Act and (ii) "relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a).

The MDA separated medical devices into three categories—Class I, Class II, and Class III—which increase in regulatory scrutiny. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–17 (2008). Even among Class III devices, there are different tiers of regulatory scrutiny. Truly new Class III medical devices go through an intense review process called "premarket approval." *Id.* at 317–18. On the other hand, a new Class III device that is "substantially equivalent" to another Class III device already on the market receives a less intensive review, during which the FDA simply confirms that the device is, in fact, substantially equivalent to an existing device. *Id.* at 317. The Supreme Court has held that the MDA's express preemption provision does not apply to Class III devices that receive only "substantial equivalence" review because the FDA does not impose specific requirements on those devices at the conclusion of the review process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493–94 (1996). But Class III devices that receive the heightened review required for premarket approval are eligible for express preemption. *Riegel*,

552 U.S. at 322–23. However, even for Class III devices that receive premarket approval, the MDA's express preemption provision does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations; "the state duties in such a case parallel, rather than add to, federal requirements." *Id.* at 330.

Some state laws that are not expressly preempted by the MDA—either because of the class status that the FDA assigned to the device or because of the parallel nature of the state law—are nevertheless impliedly preempted because the Food, Drug, and Cosmetic Act authorizes only the FDA to bring enforcement actions for violations of federal law. *See* 21 U.S.C. § 337(a). The Supreme Court has held that this exclusive grant of enforcement power to the FDA preempts any attempt by private plaintiffs to assert a cause of action premised on a violation of federal law. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 346, 348 (2001). This implied preemption applies even to devices that receive "substantial equivalence" status during the FDA clearance process rather than premarket approval. *Id.*

Under circumstances where both express and implied preemption apply, they "create[] what some federal courts have described as a narrow gap for pleadings." *Glover*, 6 F.4th at 237. In order to bring a private cause of action, "[t]he plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Id.* To determine whether express preemption applies, the Court must conduct a two-step analysis. *Koublani v. Cochlear Ltd.*, No. 20-cv-1741, 2021 WL 2577068, at *5 (E.D.N.Y. June 23, 2021). "First, the Court determines whether the FDA 'has established requirements applicable to' the device in question." *Id.* (quoting *Riegel*, 552 U.S. at 321–22). If the FDA has imposed specific requirements to the device at issue, "the second step asks the

Court to discern whether Plaintiff's 'common-law claims are based upon New York requirements with respect to the device that are different from, or in addition to, the federal ones, and that relate to safety and effectiveness.'" *Id.* (quoting *Riegel*, 552 U.S. at 321–22).

B. Express Preemption Does Not Apply to Defendants' Class II Device

Defendants' Ulthera System is classified by the FDA as a Class II device, which means that it received less regulatory scrutiny during the FDA clearance process than the types of Class III devices that the Supreme Court has held are subject to express preemption. ECF No. 17 ¶¶ 13, 35; *see Riegel*, 552 U.S. at 316–17. Nevertheless, Defendants have argued that express preemption applies to Plaintiff's claims because their device received a heightened form of Class II review known as "*de novo* review" and resulted in the FDA promulgating a "special controls" document providing guidance about the device. ECF No. 18-1 at 9–10. Defendants argue that this special controls document imposes the type of specific requirements that trigger express preemption under the MDA. *Id.*

The parties have not identified any cases in which a court has addressed whether the FDA's heightened *de novo* review process for certain types of Class II devices triggers the same express preemption that applies to Class III devices that receive premarket approval. The Court has identified only one case raising this issue, in which the court declined to apply express preemption to the defendant's Class II device because it found that it did not have enough information at the motion to dismiss stage to decide the issue. *See Tuttle v. Dexcom, Inc.*, No. 20-cv-4744, 2021 WL 8998920, at *5–6 (N.D. Ga. May 20, 2021). The Ninth Circuit has declined to apply express preemption to a Class II medical device, for which the FDA promulgated a special controls document, although the court's opinion was silent about whether that device had undergone the same *de novo* FDA review as Defendants' Ulthera System. *In re Bard IVC Filters Prod. Liab. Litig.*, 969 F.3d 1067, 1074 (9th Cir. 2020). The Ninth Circuit

decided that the special controls document applicable to the device did not trigger express preemption because the special controls at issue were not "specific requirements applicable to a *particular* device," as is required for express preemption to apply. *Id.* (emphasis in original). Instead, the special controls exhibited a "lack of specificity" and merely "reflect[ed] important but entirely generic concerns about device regulation generally." *Id.*

The Court likewise holds here that Plaintiff's claims are not expressly preempted because the FDA's special controls document on which Defendants rely does not impose any specific requirements on the Ulthera System. *See* ECF No. 18-6. Instead, the document recommends the types of tests that other manufacturers should perform when applying to the FDA for clearance to sell substantially equivalent devices. *Id.* at 7–11. To the extent the document imposes any requirements at all, it requires Defendants (and other manufacturers) to comply with the FDA's general regulations regarding device labeling. *Id.* at 11–12. Consistent with this interpretation, the only purportedly specific requirements that Defendants have attributed to the special controls document are "specific information in the labeling" required for the Ulthera System and similar devices. ECF No. 18-1 at 9.

Although Defendants have identified some cases in which courts have applied the MDA's express preemption provision to Class II medical devices, none of those cases are applicable to Plaintiff's claims in this case. *See* ECF No. 18-1 at 7–8. In all of these cases, the courts held that a plaintiff's challenge to an allegedly misleading label for a Class II medical device was preempted because the FDA had specifically defined the content required for the device's label through a regulation or a specific requirement in a special controls document. *See Papike v. Tambrands Inc.*, 107 F.3d 737, 740–41 (9th Cir. 1997); *Degelmann v. Advanced Medical Optics Inc.*, 659 F.3d 835, 841–42 (9th Cir. 2011); *Rasheed v. Church & Dwight Co.*,

No. 11-cv-80, 2012 WL 262619, at *7–8 (E.D. Tex. Jan. 12, 2012), *report and recommendation adopted in full*, 2012 WL 262616 (E.D. Tex. Jan. 30, 2012).[2] Notably, in two of these cases, the courts did not apply express preemption to other state law claims that the plaintiffs had asserted, which were unrelated to the devices' labels, and instead rejected those claims on the merits at the summary judgment stage. *Papike*, 107 F.3d at 743–44 (not applying express preemption to plaintiff's claims for design defect, negligence, and breach of express and implied warranties); *Rasheed*, 2012 WL 262619, at *3–7 (not applying express preemption to plaintiff's claims for design defect, manufacturing defect, negligence, and breach of express and implied warranties). None of the cases on which Defendants rely dealt with a Class II device that received *de novo* review, and therefore no court in those cases held that the heightened scrutiny associated with the FDA's *de novo* review process automatically triggers express preemption, as Defendants argue. Since, as described in the remaining sections of this order, none of Plaintiff's claims that survive Defendants' motion to dismiss challenge the adequacy of Defendants' label for the Ulthera System, Defendants' cases do not support applying express preemption to Plaintiff's claims.

The Court's holding that express preemption does not apply is consistent with two instances of prior litigation involving Defendants' Ulthera System. In seeking to dismiss the

[2] More specifically, the Ninth Circuit in *Papike* held that express preemption applied to failure to warn claims that challenged the adequacy of labels on defendant's Class II product because the FDA had promulgated a specific regulation, 21 C.F.R. § 801.430, applicable to the product that "mandate[d] the specific substantive content of the . . . warnings." *Papike*, 107 F.3d at 740–41. A magistrate judge in *Rasheed* similarly recommended granting summary judgment dismissing a *pro se* plaintiff's challenges to the content of the warning labels for defendant's Class II product because another FDA regulation, 21 C.F.R. § 801.435, "specifically regulate[d] labels and warnings" for that particular product. *Rasheed*, 2012 WL 262619, at *7–8. In *Degelmann*, the Ninth Circuit held that express preemption applied to claims, based on multiple California consumer fraud statutes, asserting that the label on defendant's Class II product was misleading because the FDA had published a "special controls" document that required a specific label. *Degelmann*, 659 F.3d at 841–42.

plaintiff's claims in one of these cases, Defendants argued only that implied preemption applied, and the court did not even consider applying express preemption. *See Tryan v. Ulthera, Inc.*, No. 17-cv-2036, 2018 WL 3955980, at *4 (E.D. Cal. Aug. 17, 2018). In a more recent case, the court granted in part Defendants' motion to dismiss and, in doing so, held that express preemption applied to several of the plaintiff's claims. *See Foran v. Ulthera, Inc.*, No. 20-cv-267, 2022 WL 507271, at *6–9 (E.D. Cal. Feb. 18, 2022). However, the court in that case did not address the Class II status of Defendants' device or explain why express preemption could apply to such a device in the face of the Supreme Court's holding in *Lohr* that even some Class III devices are not eligible for express preemption. *See id.* Accordingly, the Court does not consider the application of express preemption in *Foran* to be persuasive.

II. Plaintiff's Claims Related to Alleged Manufacturing Defects Are Dismissed

Even though Plaintiff's claims are not expressly preempted by the MDA, some of them nevertheless fail to state a claim. The Court dismisses Plaintiff's strict liability claim regarding an alleged manufacturing defect because Plaintiff's allegations related to this claim are conclusory and fail to allege the applicable manufacturing defect.[3] To assert a manufacturing defect claim, a plaintiff must "allege that the particular product administered to her had a defect as compared to other samples of that product" and "must therefore plead that a specific product unit was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction, and that the defect was the cause of plaintiff's injury." *Koublani*, 2021 WL 2577068, at *11 (dismissing manufacturing

[3] Although some allegations in Plaintiff's complaint appear to be more suggestive of an alleged design defect than an alleged manufacturing defect, Plaintiff's opposition brief expressly states that Plaintiff "does not allege and/or oppose dismissal of design defect claims." ECF No. 25 at 30.

defect claim). "[A] claim devoid of allegations that a particular unit differed when compared to others in the same product line will be dismissed." *Oden v. Boston Sci. Corp.*, 330 F. Supp. 3d 877, 890 (E.D.N.Y. 2018) (dismissing manufacturing defect claim).

Plaintiff simply alleges that Defendants failed to comply during the manufacturing process with 21 C.F.R. § 820.100(a), a regulation promulgated by the FDA. ECF No. 17 ¶ 226. That regulation, in turn, simply states that "[e]ach manufacturer shall establish and maintain procedures for implementing corrective and preventive action." 21 C.F.R. § 820.100(a). The regulation lists examples of what types of issues those procedures should address but does not mandate specific procedures. *Id.* These allegations "amount to a threadbare recital of the elements of a manufacturing defect cause of action" because the purported process failures do not actually identify a supposed manufacturing defect. *Koublani*, 2021 WL 2577068, at *11. Even assuming that Defendants did violate the FDA's guidance regarding CGMPs, Plaintiff has "fail[ed] to establish the necessary link between Defendants' alleged federal violations and her alleged causes of action" because she does not allege how the failure to follow CGMPs led to a defect. *Webb v. Mentor Worldwide LLC*, 453 F. Supp. 3d 550, 561 (N.D.N.Y. 2020) (dismissing manufacturing defect claims).

Plaintiff argues that she can invoke CGMPs to assert her manufacturing defect claim, but the cases on which she relies do not support allowing a plaintiff to state a manufacturing claim solely based on an alleged failure to follow CGMPs. Instead, in these cases, the plaintiffs relied on defendants' alleged failures to follow CGMPs as a means of invoking a federal requirement to avoid express preemption and then supported their allegations that a manufacturing defect actually existed by identifying additional facts suggestive of a manufacturing defect, such as recalls of the defendants' products. *See Kaemmlein v. Abbott Labs.*, 564 F. Supp. 3d 58, 63–64,

69–70 (E.D.N.Y. 2021) (denying motion to dismiss where the device at issue had been recalled "due to [a] battery manufacturing defect"); *Simoneau v. Stryker Corp.*, No. 13-cv-1200, 2014 WL 1289426, at *8 (D. Conn. Mar. 31, 2014) (denying motion to dismiss because plaintiff's complaint alleged "the specific conduct which violated these requirements [*i.e.*, the CGMPs]" and also included a "description of evidence such as FDA-classified recalls"); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 156–57 (S.D.N.Y. 2011) (denying motion to dismiss where the complaint described a "warning letter" that the FDA had sent to defendant about one manufacturing facility and a "voluntary recall" that defendant had conducted at another manufacturing facility).

Certain of Plaintiff's allegations related to her negligence claim incorporate her manufacturing defect theory. *See, e.g.*, ECF No. 17 ¶ 149 ("Defendants failed to comply with federal current good manufacturing practice (CGMP's) requirements."). "Under New York law, a [p]laintiff's claim[s] based upon an alleged design defect or manufacturing defect sounding in either negligence or strict liability are functionally equivalent and will be analyzed concurrently, in the sense that a fatal flaw in the strict liability allegations likely defeats the negligence claim as well." *Koublani*, 2021 WL 2577068, at *14 (dismissing negligence claims). Accordingly, to the extent Plaintiff's negligence claim is based on an alleged manufacturing defect, the Court dismisses those aspects of Plaintiff's negligence claim.

Plaintiff's claim for breach of an implied warranty is also partially based on an alleged manufacturing defect because Plaintiff alleges that Defendants' Ulthera System "was adulterated and manufactured in violation of federal law and regulations." ECF No. 17 ¶ 144. In order to state a claim for breach of an implied warranty, a plaintiff must "allege the following three elements: (1) that the product was defectively designed or manufactured; (2) that the defect

existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect was the proximate cause of the injury." *Kaemmlein*, 564 F. Supp. 3d at 75. Since Plaintiff has disclaimed any reliance on a design defect theory, *see* ECF No. 25 at 30, and her conclusory allegations of an alleged manufacturing defect are inadequate, she "ha[s] not pled specific facts in support of [her] breach of implied warranty claim," *see Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 260 (E.D.N.Y. 2014) (granting motion to dismiss); *see also Babayev v. Medtronic, Inc.*, 228 F. Supp. 3d 192, 219–20 (E.D.N.Y. 2017) (holding at summary judgment stage that even if plaintiff's implied warranty claims were not preempted, they failed to state a claim because "Plaintiff conclusorily allege[d] that the System and/or its components were defective or adulterated" and therefore "d[id] not allege plausible facts that even suggest[ed] the nature of the defect or adulteration").

III. Some of Plaintiff's Claims Based on Alleged Misrepresentations and Failures to Warn Survive Dismissal

Plaintiff's remaining claims, regardless of how they are labeled, are all based on Defendants' alleged statements that the Ulthera System: (i) would not cause serious adverse effects; (ii) could be used on the "full face"; and (iii) had been "approved" by the FDA. Specifically, Plaintiff incorporates her allegations that Defendants concealed alleged adverse events related to the Ulthera System into her claims for breach of express warranty, negligence, misrepresentation by omission, and strict liability for failure to warn. ECF No. 17 ¶¶ 132, 149, 177, 182, 210. She incorporates her allegations regarding Defendants' alleged off-label marketing of the Ulthera System for use on the "full face" into her claims for breach of express warranty, negligence, and strict liability for failure to warn. *Id.* ¶¶ 132, 149, 196. Although Plaintiff has not expressly linked Defendants' alleged statements that the Ulthera System was "FDA approved" to one of her specific causes of action, she has alleged that such statements

were "false[]" and were relayed to her by medical personnel at the office where she received treatment using the Ulthera System. *Id.* ¶¶ 76, 102.

The Court dismisses Plaintiff's claims to the extent they are based on Defendants' alleged off-label marketing promoting the use of the Ulthera System for the "full face." *See* ECF No. 17 ¶¶ 65–77. Even though the FDA declined to clear Defendants' marketing of the Ulthera System for this particular use, the Supreme Court in *Buckman* explained that the FDA, rather than private plaintiffs, is responsible for deciding whether to enforce prohibitions related to off-label promotion. *See Buckman*, 531 U.S. at 349–50 (explaining that the FDA's tolerance of off-label use "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine"). Other courts in the Second Circuit have therefore relied on *Buckman* to hold that claims related to off-label marketing are impliedly preempted. *See LaFountain v. Smith & Nephew, Inc.*, No. 14-cv-1598, 2016 WL 3919796, at *7 (D. Conn. July 18, 2016) (holding that plaintiff's claims regarding off-label promotion of medical device in a manner not approved by the FDA were "impliedly preempted" because they sought "to use state law to enforce or restrain noncompliance with the federal requirements" of the Food, Drug, and Cosmetic Act); *Bertini*, 8 F. Supp. 3d at 257–58 (explaining that "off-label usage of a medical device component is a widely accepted practice").

Since Plaintiff cannot use a private cause of action to enforce federal prohibitions against off-label promotion, she must therefore demonstrate that New York law recognizes a tort that prohibits such promotion. Although the Second Circuit has not directly addressed this issue, it has said that "[t]he weight of authority both in this Circuit and elsewhere casts doubts on the viability" of claims related to off-label marketing of medical devices. *Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433, 435 n.2 (2d Cir. 2015) (affirming dismissal of claims brought under

Vermont law related to off-label promotion because defendants' allegedly improper promotional statements were not pled with sufficient particularity). The guidance available from New York courts similarly suggests that New York law does not authorize such a claim. *See Baron v. Pfizer, Inc.*, 840 N.Y.S.2d 445, 448 (3d Dep't 2007) (affirming dismissal of fraud claims brought under New York's General Business Law related to the off-label marketing of drug because "off-label use is a widespread and accepted medical practice"); *Sita v. Long Island Jewish Hillside Med. Ctr.*, 803 N.Y.S.2d 112, 114 (2d Dep't 2005) (granting motion for summary judgment dismissing medical malpractice claim because "[a]lthough marketing and promotion of the pedicle screw system was not approved by the Food and Drug Administration . . . for treating the injured plaintiff's condition, this does not prevent a physician from using the system in an 'off-label' manner"). Since Plaintiff has not provided any legal authority demonstrating that New York law allows for such a claim, the Court dismisses Plaintiff's claims to the extent that they rely on Defendants' alleged off-label marketing.

The Court, however, denies Defendants' motion to dismiss Plaintiff's claims to the extent that they are based on Defendants' alleged failure to warn the FDA about adverse events related to the use of the Ulthera System. Multiple courts in this Circuit have held that New York common law would impose liability on a medical device manufacturer for failing to provide the FDA with a warning required by federal law. *A.F. ex rel. Fogel v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 544 (S.D.N.Y. 2018) ("[T]he Court holds that a manufacturer's duty to take steps that are reasonably necessary to warn the medical community may include warning the FDA as required by the MDA."); *Kaemmlein*, 564 F. Supp. 3d at 72–73 (following the decision in *Fogel*). Plaintiff has adequately alleged that adverse events occurred, that Defendants had knowledge of these events, and that Defendants failed to report the events to the FDA. ECF No.

17 ¶¶ 81–85, 92–95. To the extent that Defendants argue that the exact circumstances related to these adverse events made them non-reportable according to the FDA's criteria, *see* ECF No. 18-1 at 20–21, that is a dispute of fact that must be resolved either on summary judgment or at trial.

Plaintiff's claims also survive to the extent they are based on Defendants' alleged failure to warn the medical community at large, in addition to the FDA, about adverse events. Multiple courts in this Circuit have held that the failure to warn the medical community about such events gives rise to a legally cognizable claim under New York law. *Scism v. Ethicon, Inc.*, No. 19-cv-1543, 2020 WL 1245349, at *5 (N.D.N.Y. Mar. 16, 2020) (refusing to dismiss negligence claim based on allegations "that defendants underreported and withheld injury rates from physicians and the FDA"); *Dunham v. Covidien LP*, No. 19-cv-2851, 2019 WL 6341179, at *5 (S.D.N.Y. Nov. 27, 2019) (denying motion to dismiss negligent misrepresentation claim because plaintiff sufficiently alleged that he "and his physician reasonably relied upon Defendant's misrepresentations and omissions regarding the safety and efficacy of Defendant's . . . products"); *Ward v. Argon Med. Devices, Inc.*, No. 17-cv-607, 2018 WL 1441314, at *5, *7 (N.D.N.Y. Mar. 22, 2018) (denying motion to dismiss misrepresentation claims based on representations that defendants "knew or should have known plaintiffs and their medical providers would rely on" and strict liability failure to warn claim based on "defendants' failure to provide adequate warnings to [plaintiffs'] medical providers").[4]

[4] The Court recognizes that the court in the *Foran* case dismissed claims against Defendants based on their alleged failure to warn the medical community about adverse events. *Foran*, 2022 WL 507271, at *7. However, that court held that such claims were expressly preempted by the MDA, *see id.*, but as explained above, the Court finds *Foran's* express preemption analysis unpersuasive. The other decisions cited in this order in which courts within this Circuit similarly dismissed claims based on a defendant's failure to warn the medical community were also based on express preemption rather than the plaintiff's failure to state a claim recognized under New York law. *See Fogel*, 346 F. Supp. 3d at 544 n.8; *Bertini*, 8 F. Supp. 3d at 256–57.

However, Plaintiff's claims fail to the extent that they are based on Defendants' alleged failure to warn her personally about the risks associated with the Ulthera System. Due to New York's learned intermediary doctrine, "the manufacturer's duty to caution against a treatment's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." *Scism*, 2020 WL 1245349, at *6 (dismissing negligent misrepresentation claim because plaintiff did not adequately allege "that her doctor relied on any misrepresentation attributable to defendants"); *see also In Re Zimmer M/L Taper Hip Prosthesis Prod. Liab. Litig.*, No. 18-md-2859, 2021 WL 3475681, at *12 (S.D.N.Y. Aug. 6, 2021) (holding at summary judgment stage that Idaho law would recognize learned intermediary doctrine, meaning that "[defendant's] duty to warn ran to [plaintiff's doctor] rather than to [plaintiff] directly"). Plaintiff therefore cannot demonstrate that Defendants had a duty to provide her with any warnings.

Finally, the learned intermediary doctrine also requires dismissal of Plaintiff's claims based on allegations that Defendants promoted their product as "FDA approved." The learned intermediary doctrine requires Plaintiff to plead her doctors' reasonable reliance on Defendants' alleged misrepresentations rather than her own reliance. *Scism*, 2020 WL 1245349, at *6. The Court finds that, unlike a patient, any reasonable doctor would have understood that the FDA's review process for Class II devices does not represent "approval," so no doctor would have reasonably relied on these alleged misstatements.[5]

[5] The Court notes that in the *Tryan* case involving Defendants' Ulthera System, the court declined to dismiss the plaintiff's claims that were based on allegations that Defendants' statements that the Ulthera System was "FDA approved" were potentially misleading. *Tryan*, 2018 WL 3955980, at *6–7. However, the court held that those statements potentially violated a California statute related to unfair business practices rather than a common law tort. *See id.* Plaintiff has not asserted an analogous claim under New York's General Business Law or any similar statute. *Cf. Oden*, 330 F. Supp. 3d at 902 (explaining that "justifiable reliance by the

CONCLUSION

The Court grants in part and denies in part Defendants' motion to dismiss, *see* ECF No. 18, for the reasons set forth above. The parties shall file on or before April 21, 2023, a proposed case management plan regarding discovery related to Plaintiff's surviving claims, along with a joint letter no longer than three pages describing the discovery that has occurred to date, including third-party discovery, and any current disputes related to such discovery.

SO ORDERED.

/s/ Hector Gonzalez
HECTOR GONZALEZ
United States District Judge

Dated: Brooklyn, New York
March 31, 2023

plaintiff is not an element" of a claim under New York's General Business Law but dismissing the claim on other grounds).